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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,511

11/14/2003

William W. Alston

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01/30/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

01/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/714,511	Applicant(s) ALSTON ET AL.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/31/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed on February 14, 2008. Examiner acknowledges claims 1-9, 11-20, 22-24, and 26-40 are pending in this application, with claims 29-40 having been newly added and claims 10, 21, and 25 having been cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-9, 11-20, 22-24, and 26-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niccolai (6,705,313) in view of Sacks (2,946,332).

As to Claims 1, 15, 22, and 26, Niccolai discloses a body defining a chamber (17) having an air inlet (20) and an outlet (9), wherein the chamber is sized to receive a receptacle (18) containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber (Figs. 1, 2) and wherein the air inlet is oriented to cause air to swirl within the chamber (Fig. 2); wherein the chamber comprises a longitudinal axis which is substantially parallel to an inhalation direction and wherein the chamber has a sidewall with a cross-section orthogonal to the longitudinal axis of the chamber and wherein the receptacle contacts the cross-section of the sidewall when the receptacle moves within the chamber (Fig. 2), whereby when a user inhales, air enters into the chamber through the inlet (20) to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with cross-section of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet (Col. 3, lines 41-58; Figs. 1, 2). Yet, Niccolai does not expressly disclose the use of a non-circular cross section. However, at the time the invention was made the use of non-circular cross sections were known. Specifically, Sacks teaches the use of a plurality of projections (32 and 30) within the chamber for maintaining the positioning of the receptacle (medicament capsule) against the walls of the chamber; thereby, enabling air to pass around the capsule for the purpose of assisting in the insufflation of medicament to the patient. (Figures 3 and 4, and Column 2, Lines 40-43, 65-70, and Column 3, Lines 19-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Niccolai to include a non-circular cross-

section on the side wall of the receptacle for the purpose of enabling the insufflation of medicament.

As to Claims 2, 16, 23, and 27, Niccolai discloses wherein the receptacle (18) is a capsule.

As to Claims 3 and 17, Niccolai discloses wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45 degrees during use (Figs. 1,2). Further, Niccolai and Sacks discloses an apparatus in which the claimed functional limitations can be performed as there is no structural elements that prevent the utilization of the aerosolizing apparatus in the recited functionality. The operational characteristics of the apparatus are functional language. While features of an apparatus may be recited wither structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. MPEP §2114.

As to Claims 4, 18, and 27, Niccolai discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (Figs. 1,2).

As to Claims 5 and 19, Niccolai discloses wherein the width of the chamber is less than the length of the capsule (Fig. 5).

As to Claims 6, 20, and 24, Niccolai discloses a puncturing member (14) moveable within the chamber to create the opening in the receptacle.

As to Claim 7, Niccolai discloses wherein the puncture member comprises a sharpened tip for penetrating the wall of the receptacle (Figs. 1, 2).

As to Claim 8, Niccolai discloses wherein the puncture member comprises a pair of sharpened tips for penetrating the wall of the receptacle (Figs. 1, 2).

As to Claim 9, Niccolai discloses wherein the puncture member is positioned to pierce only one end of the receptacle (Figs. 1,2).

As to Claims 11, 12, 29, 30, 33, 34, 37, and 38, the system of Niccolai and Sacks discloses a plurality of projections (30 and 32) that extend into the chamber from the side walls of the chamber.

As to Claims 13, 14, 31, 32, 35, 36, 39, and 40, the system of Niccolai and Sacks discloses the non-circular cross section yet does not expressly disclose the shape of the cross section in an oval or polygon shape. It would have been an obvious matter of design choice to make the different portions of the non-circular cross section of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Response to Arguments

5. Applicant's arguments, filed February 14, 2008, with respect to the rejection(s) of claim(s) 1-9, 11-20, 22-24, and 26-28 under 35 U.S.C. §102(b) as being anticipated by Niccolai have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Niccolai (6,705,313) in view of Sacks (2,946,332).

Applicant asserted the prior art made of record does not teach a non-circular receptacle for the medicament capsule. Examiner agrees the prior art Niccolai alone does not teach a non-circular receptacle for the medicament capsule. However, the combination of the prior art Niccolai and Sacks teaches portions of the sidewalls contacting the medicament capsules having a plurality of projections thereby imparting a non-circular cross section as seen in Figures 3 and 4 of prior art Sacks. Therefore, in light of the aforementioned reasoning the new grounds of rejection has been set forth.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kladders (4,889,114), Cocozza (3,906,950), and Calvert et al. (5,522,383) discloses additional capsule powder inhalers having non-circular cross sections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

/Annette F Dixon/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771